

DIN EN ISO 5364:2017-01 (E)

Anaesthetic and respiratory equipment - Oropharyngeal airways (ISO 5364:2016)

Contents

	Page
European foreword	3
Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC	5
Foreword	8
Introduction	9
1 Scope	10
2 Normative references	10
3 Terms and definitions	10
4 Size designation and dimensions	11
4.1 Size designation.....	11
4.2 Dimensions.....	12
5 Materials	12
6 Design	12
7 Performance requirements	12
7.1 Resistance to collapse of the buccal portion.....	12
7.2 Patency of lumen.....	12
8 Sterility assurance	13
9 Packaging of oropharyngeal airways supplied sterile	13
10 Marking	13
10.1 General.....	13
10.2 Use of symbols.....	13
10.3 Marking of oropharyngeal airways.....	13
10.4 Marking of unit packs.....	14
10.5 Marking of shelf or multi-unit packs.....	15
11 Information to be supplied by the manufacturer	15
Annex A (informative) Rationale	16
Annex B (normative) Test method for resistance to collapse of the buccal portion	18
Annex C (normative) Test method for patency of lumen	20
Annex D (informative) Guidance on materials and design	22
Bibliography	23